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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,137	05/15/2006	Jussi Nurmi	TUR-181	3667

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EXAMINER	
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ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,137	NURMI ET AL.	
	Examiner	Art Unit	
	STEPHANIE K. MUMMERT	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *14-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/15/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group 1, claims 1-13 in the reply filed on September 10, 2008 is acknowledged. The traversal is on the ground(s) that "the claimed method is a nucleic acid amplification assay for quantitative and/or qualitatitve analysis of the presence of a specific analyte or specific analytes in a biological sample" and note that "Burshteyn et al. Fails to disclose or suggest the nucleic acid amplification step of the claimed method" (p. 2 of remarks). This is not found persuasive because while Applicant's arguments are noted, Burshteyn teaches an apparatus or arrangement for the capture of biological particles (Abstract, p. 4-6 and Figures 1 and 4). Burshteyn also renders obvious a method which comprises a filtration device which comprises a filtration device for the capture of biological particles and expels the captured cells for analysis. While Applicant correctly notes that Burshteyn does not explicitly teach amplification of the captured biomolecules, first it is noted that the limitation "nucleic acid amplification assay" in the preamble to claim 1, without a specific step directed to amplification does not limit the method of claim 1 to amplification analysis. Furthermore, Burshteyn does teach that the captured biomolecules should be analyzed further and one of ordinary skill in the art at the time the invention was made would have readily recognized amplification of the captured biomolecules as an obvious extension of Burshteyn. Therefore, the teaching of Burshteyn indicates that the claims of the instant application are not linked by a special technical feature that distinguishes over the art.

The requirement is still deemed proper and is therefore made FINAL.

Claims 14-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 10, 2008.

Claims 1-13 are pending and will be examined.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 15, 2008 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Interpretation

The preamble to claim 1 stating "a nucleic acid amplification assay", absent an active method step directed to analysis of the captured or released analyte using amplification, will not be read as limiting the method of claim 1 to prior art which recites amplification analysis. Claim 8 is the only claim which actively recites a method step which requires analysis using PCR or other means of amplification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Cabuz et al. (US Patent 6,568,286; May 2003; 102(e) date, June 2, 2000). Cabuz teaches a filtration apparatus useful for detection of harmful biological agents (Abstract).

With regard to claim 1, Cabuz teaches a nucleic acid amplification assay for quantitative and/or qualitative analysis of the presence of a specific analyte or specific analytes in a biological sample, which analytes, if present, are contained in biological particles of said sample, in which assay the sample is forced in a first direction through a filter that retains said biological particles wherein said biological particles retained in said filter are flushed, by a flush flow in a second opposite direction through said filter out of said filter and said flush flow containing said biological particles flushed out is analysed for the analyte or analytes (col. 2, lines 39-58, where an apparatus is designed to sample fluid such as air, filtering the fluid and sampling the fluid using a sensor and where the apparatus can be used to detect airborne agents or harmful chemical or biological agents; see also col. 9, lines 61-67, where the embodiment of "shallow breathing" is described again, where it is noted that the fluid is drawn through in a bi-directional manner, past the sensor and then back through the same way it entered).

With regard to claim 2, Cabuz teaches an embodiment of claim 1, further comprising an additional filtration prior to the filtration retaining the biological particles containing the analyte or analytes, which additional filtration does not retain the biological particles containing the analyte or analytes but retains particles that might interfere with the analysis of the analyte or

analytes (col. 2, lines 46-48, where filters can also be included of the "impactor type" to trap particles that have entered the pump).

With regard to claim 3, Cabuz teaches an embodiment of claim 1, wherein the flow containing the biological particles containing the analyte or analytes flushed out is analysed for the analyte or analytes without any further purification (col. 9, lines 61-67, where the embodiment of "shallow breathing" is described again, where it is noted that the fluid is drawn through in a bi-directional manner, past the sensor and then back through the same way it entered; see also col. 10, line 65 to col. 11, line 10, where a bi-directional flow embodiment is digrammed in Figure 8).

With regard to claim 4, Cabuz teaches an embodiment of claim 1, wherein retention of the biological particles containing the analyte or analytes in the filter is essentially size dependent (col. 2, lines 46-48, where filters can also be included of the "impactor type" to trap particles that have entered the pump).

With regard to claim 5, Cabuz teaches an embodiment of claim 1 wherein retention of the biological particles containing the analyte or analytes in the filter is essentially dependent on the chemical properties of the particle (col. 7 to 8, where a variety of sensors or filters are described which capture or detect analytes dependent on chemical properties of the analyte).

With regard to claim 9, Cabuz teaches an embodiment of claim 1, wherein the biological particles containing the analyte or analytes are flushed with a liquid or a gas preferably not contained in the original sample (col. 9, lines 61-67, where the embodiment of "shallow breathing" is described again, where it is noted that the fluid is drawn through in a bi-directional manner, past the sensor and then back through the same way it entered).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-8 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cabuz et al. (US Patent 6,568,286; May 2003; 102(e) date, June 2, 2000) as applied to claims 1-5 and 9 in view of Iqbal et al. (Biosensors & Bioelectronics, 2000, vol. 15, p. 549-578). Cabuz teaches a filtration apparatus useful for detection of harmful biological agents (Abstract).

Cabuz teaches all of the limitations of claims 1-5 and 9 as recited in the rejection above. However, Cabuz refers only to biological agents and is not specific about what types of biological agents may be analyzed using the filtration and biosensor disclosed. Iqbal teaches a variety of biological agents and a variety of techniques for their detection (Abstract).

With regard to claim 6, Iqbal teaches an embodiment of claim 1, wherein the biological particles containing the analyte or analytes are selected from the group consisting of prokaryotic or eukaryotic cells or spores or components thereof, viruses or viral particles, complexes comprising protein and/or nucleic acid, and any combination thereof (p. 550, col. 1, where it is noted that biological threat agents can be infectious or toxigenic organisms or simply toxins, including anthrax or plague; see Scheme 1, where bacteria, spores, viruses and toxins are depicted as relevant targets or analytes).

With regard to claim 7, Iqbal teaches an embodiment of claim 6, wherein the biological particles containing the analyte or analytes are selected from the group consisting of bacteria, bacterial cell, plant pollen, mitochondria, chloroplast, cell nuclei, virus, phage, chromosome and ribosome (p. 550, col. 1, where it is noted that biological threat agents can be infectious or toxigenic organisms or simply toxins, including anthrax or plague; see Scheme 1, where bacteria, spores, viruses and toxins are depicted as relevant targets or analytes).

With regard to claim 8, Iqbal teaches an embodiment of claim 1, wherein the means of analysing the analyte or analytes is selected from the group consisting of polymerase chain reaction (PCR), reverse transcriptase polymerase chain reaction (RT-PCR), ligase chain reaction (LCR), proximity ligation assay, nucleic acid sequence based amplification (NASBA), strand displacement amplification (SDA) and any combination thereof (p. 555, where target amplification techniques are described and include PCR and LCR in addition to a variety of other techniques).

With regard to claim 10, Iqbal teaches an embodiment of claim 1 wherein the analyte or analytes are selected from the group consisting of a living and/or dead cell or virus; a peptide, a protein or complex thereof; a nucleic acid; and any combination thereof (p. 550, Scheme 1, where the target analytes are analyzed using nucleic acids or antigens).

With regard to claim 11, Iqbal teaches an embodiment of claim 10, wherein the analyte or analytes comprises living and/or dead cells and/or viruses selected from the group consisting of a mold, a yeast, a eukaryotic cell or organism, a pathogenic virus and a cancer cell (p. 550, col. 1, where it is noted that biological threat agents can be infectious or toxigenic organisms or simply

toxins, including anthrax or plague; see Scheme 1, where bacteria, spores, viruses and toxins are depicted as relevant targets or analytes).

With regard to claim 12, Iqbal teaches an embodiment of claim 10, wherein the analyte or analytes comprises nucleic acids selected from the group consisting of DNA, RNA and any derivative thereof (p. 550, Scheme 1, where the target analytes are analyzed using nucleic acids or antigens).

With regard to claim 13, Iqbal teaches an embodiment of claim 10, wherein the analyte or analytes comprises peptides and/or proteins or complexes thereof selected from the group consisting of a hormone, a growth factor, an enzyme or parts thereof and/or complexes thereof; and any combination thereof (p. 550, Scheme 1, where the target analytes are analyzed using nucleic acids or antigens).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have applied the specific harmful biological agents described in detail by Iqbal to the method of capture and analysis of biological and chemical agents as taught by Cabuz. Cabuz taught generally, "the integrated mesopump sensors can provide a large number of small, lightweight and closely spaced sensors that can be used advantageously to detect airborne agents, including harmful chemical and biological agents or trace amounts of TNT or other explosives" (col. 2, lines 49-53). As taught by Iqbal, "identification of biological threat agents involves recognition of bacteria (vegetative cells and spores) viruses and toxins" (p. 550, col. 2). Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to have applied the specific harmful biological agents described in detail by Iqbal

to the method of capture and analysis of biological and chemical agents as taught by Cabuz to achieve capture and detection of analytes with a reasonable expectation for success.

Conclusion

All claims stand rejected, no claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEPHANIE K. MUMMERT whose telephone number is (571)272-8503. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephanie K. Mummert/
Examiner, Art Unit 1637

SKM